ophthalmic community and the requirement of the agency that all these lenses be somehow incorporated into the IDE.

DR. VAN METER: Van Meter. Well, post-market surveillance would not necessarily delay other surgeons being able to use this device; would it? It just means that we would still collect data while making the device available to other surgeons.

DR. ROSENTHAL: Rosenthal. Yeah, but the data collection might be considered not least burdensome on over 500 patients.

DR. VAN METER: We don't want to inconvenience the sponsor's collection of data.

DR. ROSENTHAL: No, you've already heard their difficulty in collecting the data on the--I forget how they named these groups--but on groups that were added on as other arms, which the sponsor did because of our request for this demand, and we asked them to use that data to support safety more than really to support the efficacy of the device.

DR. VAN METER: But we're talking about some long-term concerns that would not necessarily show up in two years time.

DR. ROSENTHAL: No, but I'm not talking on

the length of time. I'm talking on the number of patients.

DR. SUGAR: What about Core I?

DR. ROSENTHAL: You said all the patients in all the core groups.

DR. VAN METER: What about just the first --

DR. ROSENTHAL: Well, that's 540 patients.

DR. VAN METER: Well, I amend my motion to post-market surveillance of the original 75 patients in the core group Phase I.

DR. WEISS: For how long? Or at what point?

DR. VAN METER: Five years.

DR. WEISS: Five years. Dr. Bradley and then Dr. McMahon.

DR. BRADLEY: There are two ways in which you can do post-market monitoring of patients. One is you can have pertinent ophthalmologists give feedback to the company on any adverse events in that original cohort. Or you can proactively bring these people in on an annual basis and examine them. Are we suggesting one or the other of those options?

DR. WEISS: Dr. Van Meter.

DR. VAN METER: I feel like I'm talking too much about this. If no one else shares my concern, you know, I don't want to push it.

DR. GRIMMETT: Mike Grimmett. I think regarding Dr. Bradley's distinction, the first option, I think, is already in the system. Adverse device reporting is already in existence for physicians who see some patient come in with a problem on an approved device. So I think the intent of Dr. Van Meter's motion is to drag them in on an annual basis and examine them rigorously.

DR. WEISS: Dr. Rosenthal, did you have a comment?

DR. ROSENTHAL: My only comment--Rosenthal--the MDR reporting, as you know, is seriously under reported, and particularly in ophthalmology. It's almost nonexistent except if you have to explant and even then we collect better data from Dr. Apple than we get from our own system. So--

DR. WEISS: Dr. McMahon and then Dr. Matoba.

DR. McMAHON: My understanding is this device has been available also for up to ten years now, and I haven't been aware of a crescendo of

concern outside the United States with this device. So maybe that's where some of the hesitancy here is arising in doing a post-market approval study.

DR. WEISS: I think that we might as well just put this motion to a vote so that we can move on, unless you have any other amendments to the motion, Dr. Van Meter?

DR. VAN METER: No. Let's vote and move on.

DR. WEISS: Can we have the motion restated, Dr. Grimmett? Would you be able to do that for us?

DR. GRIMMETT: Sure. Dr. Van Meter is suggesting post-market surveillance to five years in the original Core I group of 75 patients, primarily to evaluate lens centration; is that correct?

DR. VAN METER: Yes.

DR. WEISS: All in favor? Yes, Dr. Van Meter.

DR. VAN METER: Let me just make one mention that I believe we're down to 50 patients already at two years.

DR. WEISS: Okay.

DR. VAN METER: And so it's probably going

to be less than 75 patients who we get information on in five years.

DR. ROSENTHAL: Rosenthal. I think you can request for the cohort, core cohort. It may be that 50 have reached two years, and the other 25 are between one and two and will ultimately get to two years.

But my understanding of this is that you want them called in and examined?

DR. VAN METER: Right. I'm referring to the cohort, but I understand that there were a number of dropouts, you know, discontinuations and lost to follow-ups, in that first cohort already.

And so it really will be less than 75 patients that the sponsor would be responsible for.

DR. ROSENTHAL: Rosenthal. Do you feel you would get the information you require on the smaller number of patients if it is decentrated? Continues to decentrate?

DR. VAN METER: Yeah. I would love to have longer data on some patients and I don't have --you know, we haven't seen any long-term data on the foreign patients, and I don't think two years is appropriate to say that the decentration is stable.

DR. WEISS: I would suggest that we vote at this point. Everyone in favor of the motion please raise your hands.

[Show of hands.]

DR. WEISS: Motion does not--three--I think Dr. Smith just raised her hand. Motion does not--

DR. ROSENTHAL: No, no. You have to vote. Ask for against and then abstain, please.

DR. WEISS: Okay. Can we have all those against?

[Show of hands.]

DR. WEISS: Three, four, seven against. The motion does not pass. I will mention one or two other items that I had scribed before we go on unless there's any other additional items that anyone wants to come up with at this point before we go on to labeling issues including the physician information booklet as well as contraindications.

The other item I had down here which may have already been--well, this probably would fall under labeling--is the information on the different sizes of the rings used and the data to suggest the sizes. Has that been already indicated?

DR. GRIMMETT: We were going to talk about

that, I think, in the context of the physician information booklet.

DR. WEISS: Okay.

DR. GRIMMETT: As a piece of information that would be valuable in that document.

DR. WEISS: Fine. Any other items that anyone would like to bring up on the panel before we get on to labeling? Dr. Sugar?

DR. SUGAR: Dr. Matoba showed me where there is data in our data packet on the types of intraocular lenses that were implanted so that does not need to be requested. My mistake.

DR. WEISS: Okay. So we will eliminate that from the list of items we would desire. The other thing that I will ask the panel is something that I brought up previously, the question of information on additional analysis on the existing cohort regarding vitreous loss, dislocation of the nucleus, ability to implant a PC IOL, those three items.

Does anyone from the panel want those items and if so if they would put a motion forward, and if they don't want those items, we can leave that aside.

Okay. I don't think there's any interest

in those items. So we will now go on to labeling issues. Any motions regarding labeling? Dr. Sugar?

DR. SUGAR: Does the scribe have the suggestions listed?

DR. WEISS: In this case, I was the unwilling scribe, I think.

DR. SUGAR: Does Madam Scribe have those?

DR. WEISS: Yeah. The things that I have listed here are a statement that no evidence that the ring alters progression of zonular instability.

Any motions concerning that?

DR. SUGAR: So moved.

PANEL MEMBER: Second.

DR. WEISS: Second. Any discussion? If there is no discussion, I would ask all those in favor of the motion to raise their hand.

[Show of hands.]

DR. WEISS: I think it's unanimous. That motion passes. As regards to labeling, I had introduced a suggestion that a contraindication to the device be listed as not to be used in a subsequently to be determined number of clock hours of zonular dehiscence. For example, as Dr. Steinert mentioned, he wouldn't use it in more than

four hours zonular dehiscence or if there is any information from the sponsor in the future to change it to a different clock hour, three and a half, four and a half, whatever.

Any discussion on that or any motion along that line? Does anyone want to list that as a contraindication or leave that elsewhere?

DR. BRADLEY: Jayne.

DR. WEISS: Dr. Bradley.

DR. BRADLEY: I recall the discussion that we've had. We don't really have data or don't have very much data regarding a contraindication for patients with too many clock hours missing, but we have data of successes; is that correct?

So I'm wondering if rather than a contraindication, one should put it in as an indication of the type of zonule problems for which the lens has been--sorry--for which the device has been proven to be effective?

DR. WEISS: Well, my individual concern as a clinician is that even if we don't have data, that you should not use this in someone who is, let's say, nine clock hours of dehiscence. If the experience of the clinicians who are experienced in this are you would not want to use it, then I think

there might be some advantage to put that out loud and clear to allow people to know what the limitations of this device are without having to read the fine print.

Dr. McMahon.

DR. McMAHON: Would you entertain it as a caution rather than a contraindication since the definable clock hours have not really been elucidated at this point?

DR. WEISS: Yes, I think that's a good suggestion. Does anyone have a motion as regards to this issue? Dr. Sugar?

DR. SUGAR: I'd like to move that the labeling includes a statement that caution should be exercised when using this, if using, if considering using this device in large areas of zonular weakness or absence, or partial absence, especially that greater than four clock hours. But, you know, that's taken from what Roger said, but I don't--you know, he said three to four clock hours, I believe.

Sorry. He said three to four clock hours, I believe. I feel uncomfortable making that statement because we're asking for the data from which maybe we can make that statement. So if

there is a more vague way of saying it, I would prefer it.

DR. VAN METER: Is it possible to ask sponsor to provide a guide for the amount of clock hours for which the device is indicated?

DR. WEISS: Yes, we can. So, Ralph, can we scribe it leaving out the exact number of clock hours that the precautionary note is going to?

DR. ROSENTHAL: Rosenthal. Yes, I think that's quite reasonable. And I think one of your conditions has already been to get some idea of clock hours. So we can also send that out to our clinical reviewer.

DR. WEISS: Okay. So would like to restate that again, Joel, and then make it--why don't you restate then.

DR. GRIMMETT: Yeah, Mike Grimmett. We have a two-part motion. Part A was sponsor to provide additional information regarding how many hours of clock hours of zonular dehiscence were observed in this study. And Part B was caution is advised if using this device with large areas of zonular dehiscence.

DR. SUGAR: So moved.

DR. SMITH: Second.

DR. SUGAR: So moved.

DR. SMITH: Second.

DR. WEISS: Can we have a vote all--if there is no discussion, a vote--do you have a comment, Dr. Ho?

DR. HO: No.

DR. WEISS: You were voting before we even called the vote. You're enthusiastic on this one.

[Laughter.]

DR. WEISS: So we will have a vote. All in favor?

[Show of hands.]

DR. WEISS: Okay. I think that passes unanimously. As far as other labeling issues, the other issues I had here--anyone else have any other labeling issues, because the other issues that I had were basically--that I had scribed before basically referred to the physician information booklet.

DR. GRIMMETT: This is Mike Grimmett.

DR. WEISS: Dr. Grimmett.

DR. GRIMMETT: I think Dr. Smith wanted to remove, and Dr. Ho agreed, remove the BDR contraindication statement.

DR. HO: And glaucoma.

DR. COLEMAN: Dr. Coleman. And glaucoma.

DR. GRIMMETT: And glaucoma.

DR. SMITH: I move to remove the three lower indication--three bottom contraindications from the labeling information.

DR. GRIMMETT: For the record, can you list the three lower ones?

DR. VAN METER: Glaucoma.

DR. SMITH: Chronic uveitis, diabetic retinopathy.

DR. VAN METER: The other one was progressive eye disease.

DR. SMITH: Progressive eye disease.

DR. COLEMAN: This is Dr. Coleman. Are you also going to remove operative complications such as bleeding?

DR. SMITH: I don't propose to remove operative complications. So the motion then is to remove the contraindications of glaucoma, diabetic retinopathy, progressive eye disease, and uveitis.

DR. WEISS: Okay. And that motion was seconded. Yes, Dr. Matoba.

DR. MATOBA: So while we're removing contraindications, you were going to remove the first year of life also and substitute an

indication 18 years or older.

DR. GRIMMETT: Mike Grimmett. The 18 year old went into the original indication statement where Dr. Sugar added in patients aged 18 years or older.

DR. MATOBA: Move to remove the first year of life, that contraindication?

DR. GRIMMETT: Sure.

DR. WEISS: Is that all right with you, Dr. Smith?

DR. SMITH: Yes.

DR. WEISS: Okay.

DR. SMITH: So the motion then is actually to remove all the contraindications that are listed except for the intraoperative complications.

DR. WEISS: Okay.

DR. SMITH: Under contraindications, there will be only one listed, and that is intraoperative complications.

DR. WEISS: Okay. And that's seconded. That was seconded. We can vote on that, then. All in favor, raise your hand.

[Show of hands.]

DR. WEISS: That appears unanimous. That's passed.

DR. SUGAR: I'd like to make a motion to remove the intraoperative complications.

DR. WEISS: And is it seconded?

DR. COLEMAN: I second it.

DR. WEISS: Okay. Any discussion on removal of the list of intraoperative complications from the sponsor's? If there is no discussion, we can vote on this.

Everyone in favor, please raise their hand.

[Show of hands.]

DR. WEISS: Why don't we have that motion restated? Can you restate the motion? Or Dr. Grimmett, can you restate the motion?

DR. GRIMMETT: Sure. Remove from--in the labeling from the contraindication section remove the statement that it's contraindicated with intraoperative complications, and I think it was previously stated such as bleeding.

DR. WEISS: Perhaps we can have Dr. Van Meter if--

DR. SUGAR: Could I restate my motion?

DR. GRIMMETT: Sure.

DR. SUGAR: I'd like to remove the contraindication that operative complications in

cataract operations (prolapse of the vitreous body, bleeding) be removed.

I don't know if it was seconded or not.

DR. COLEMAN: I second.

DR. WEISS: Dr. Coleman seconded it.

DR. SUGAR: I'd just like to discuss that there can be vitreous prolapse around a small area of zonular dehiscence. You can do a vitrectomy around it and still put in the device and put in an implant, and I don't know that that's so unusual.

DR. COLEMAN: Dr. Coleman. In terms of if you do iris stretching to make the pupil larger or if you do any spinctorotemies, you're going to have bleeding. So I think that that would be an opportunity to not have it available to physicians to have it as a contraindication.

DR. WEISS: Any other discussion on this, motion? If not--Dr. Ho, you have any concerns about this motion?

DR. HO: No.

DR. WEISS: No. Okay. If not, why don't we put this to a vote. All of those in favor, please raise your hand.

[Show of hands.]

MS. THORNTON: Eight for and two against.

DR. WEISS: All those against?

[Show of hands.]

DR. WEISS: Okay. The motion passes. Any other labeling issues?

DR. HO: Yes.

DR. WEISS: Dr. Ho.

DR. HO: It's not included already and I don't have our list. Perhaps in the warning section, I would just like to make a simple statement that the long-term effect of the capsular tension ring on the stability of the capsule bag is--

DR. WEISS: I think we've already had that.

DR. GRIMMETT: Mike Grimmett. It's already in.

DR. WEISS: Okay. Any other labeling issues? If there are no other labeling issues, then I think we'll proceed to the physician information booklet.

Yes, Dr. Grimmett.

DR. GRIMMETT: Mike Grimmett, just one question. Maybe already done. We've already eliminated that it's indicated for high myopia somewhere in there or that's been stated in another

question. Done.

DR. WEISS: I would actually ask this to the panel. Do we need to eliminate the list of pseudoexfoliation, high myopia, trauma and such, or has that already been successfully performed by changing the indication?

DR. McMAHON: I think it's the latter.

DR. WEISS: Successfully performed. Okay. As far as the physician information--well, actually before we go to the physician information booklet, I don't recall if we've addressed the idea of a patient card in any motion yet, a patient card such as an IOL type card, that a patient be given if they've had this implanted.

DR. SUGAR: So moved.

DR. VAN METER: Second.

DR. WEISS: Okay. Any discussion? Vote? Everyone in favor, raise your hand.

[Show of hands.]

DR. WEISS: The motion passes. Now I think we can go on to the physician information book. I will just sort of run through some of the scribing that I did and then I would ask some members of the panel to take this forward as motions.

What was talked about previously as having/being put in the physician information booklet was data and information to suggest to the physician the indications for the use of each of the individual three sizes of this product. Perhaps we should do it one by one.

Would that be agreed to? Anyone want to put a motion forward?

DR. McMAHON: So moved.

DR. SUGAR: Second.

DR. WEISS: Can we have a hand vote? Those who agree, in favor?

[Show of hands.]

DR. WEISS: This is data on the size. Then it was also suggested that insertion and removal technique for the device be placed in the physician information booklet.

DR. McMAHON: Question?

DR. WEISS: Yes, Dr. McMahon.

DR. McMAHON: I'm not knowledgeable of this. Is this standard for other device insertion procedures like implants and so forth?

DR. WEISS: Dr. Rosenthal.

DR. ROSENTHAL: I don't think we tell the surgeon how to implant an intraocular lens. This

is a first of a kind. I think if the panel feels that it's appropriate to put it in because of some complexity or some issue regarding when it's best to do so or how best to proceed, I think it's quite reasonable. If the panel feels that it should be done, it should be done.

DR. WEISS: Yeah. Dr. Van Meter.

DR. VAN METER: Dr. Steinert this morning showed us that there were several ways to put it in, one using a plunger to put it in, another inserted freehand. Some of this would be determined by surgeon preference and incision size, and I think maybe we should request a description or several alternative ways that you can implant the device, and then maybe let the surgeon pick which of those methods best suits his particular situation at the time of implantation.

DR. WEISS: This could be alternatives for methods for insertion and removal.

DR. VAN METER: Right. Describe how you do it with a plunger and describe how you do it freehand.

DR. WEISS: Okay. Dr. Smith.

DR. SMITH: The other issue is that there was material provided in the packet from Dr.

Witschel which says that the ring needs to be inserted, this visco-elastics, and if it's being inserted prior to hydra dissection, that is not-- that will not be true.

DR. WEISS: Well, we use visco elastic prior to hydra dissection. So that's--

DR. SMITH: Well, I think what Dr. Witschel wrote basically that the lens was removed and that there's visco-elastic in the posterior capsular bag. So since there is some difference, I agree with Dr. Van Meter that alternate approaches should be presented to the physician.

DR. WEISS: Okay. Does someone want to restate this motion? Dr. Grimmett.

DR. GRIMMETT: In the physician information booklet provide data and information regarding insertion and removal technique for the ring including both manual and quote-unquote "shooter techniques," if available.

DR. WEISS: Okay. Is that seconded? Okay. Can we have a vote? All in favor? Yes, Dr. Bradley.

DR. BRADLEY: As a non-surgeon, it just seems to me that it's quite useful perhaps to the sponsor to provide that sort of information to

potential customers, but I wonder how that impacts the safety and efficacy of the device? Do we have reason to believe those instructions will? Is it upon that assumption or belief that we would require the sponsor to put this in the physician's --

DR. WEISS: Well, I would think if you know how to implant the device properly, it would have a higher potential to be safe and efficacious.

DR. SMITH: Janine Smith. But they also did not provide that information. I specifically asked that. We don't know how these were implanted. So there's no data to tell us. Some surgeons may have used one technique and others the opposite technique. So there is no data available to us regarding that.

DR. SUGAR: Any data they put in will be more than they have now.

DR. SMITH: Well, I don't think that data exists. It wasn't on the data collection.

DR. WEISS: But we may not have the data, but we're asking for advice on how to insert it, and I think that--well, I think that's a reasonable motion to make and then we can have a vote on that motion. So why don't we bring that to vote?

All those in favor of requiring the sponsor to put in insertion and removal techniques in labeling the physician's information booklet signify by raising your hand.

[Show of hands.]

DR. WEISS: Seven in favor. All those opposed, raise your hand.

[Show of hands.]

DR. WEISS: And all those abstaining?

[Show of hands.]

DR. WEISS: We're still missing one vote. Maybe if we can just repeat it. All those in favor please raise your hand.

[Show of hands.]

DR. WEISS: Okay. Now the numbers add up. The other thing that was listed as far as labeling --some of these may actually be repeated in things that we've already moved forward--are an outcomes analysis including complications and adverse events. Has that already been--

DR. ROSENTHAL: Dr. Rosenthal.

DR. WEISS: Dr. Rosenthal.

DR. ROSENTHAL: That's done pretty automatically.

DR. WEISS: Okay. So we don't need that.

Another--

DR. ROSENTHAL: I mean I'd be happy to have your recommendation, but we would--

DR. WEISS: You would standardly do that even without our recommendation?

DR. ROSENTHAL: I think it's pretty standard we put in.

DR. WEISS: Okay. If you do it without a recommendation, then we don't need to discuss that. Indications for use of the device? That was listed. I mean I think we've probably taken care of that by the initial phrasing.

Dr. Grimmett.

DR. GRIMMETT: Mike Grimmett. I think the intent of that was is because we took our Marfan's, pseudoexfoliation, those things, just now to mention it in the physician information booklet that these are conditions where you might see zonular weakness, some statement like that.

DR. WEISS: Okay. Would you like to put that forward in the form of a motion?

DR. VAN METER: I would move that we include Marfan's, pseudoexfoliation, traumatic--we include pseudoexfoliation syndrome, primary zonular weakness/dehiscence, i.e., Marfan's,

homocysteneria, secondary zonular weakness dehiscence (trauma), and eyes following vitrectomy as the four indications where this device might be found most useful.

DR. WEISS: Is this motion seconded?

DR. CASEY: Second.

DR. WEISS: Dr. Casey seconds the motion. Any discussion? Dr. Sugar.

DR. SUGAR: Is there any data on homocysteneria?

DR. VAN METER: I was including that as--

DR. SUGAR: I know, as a--I'd rather absent data not list it because we have data on those other things.

DR. VAN METER: Well, that's why I was using primary zonular dehiscence and just use--okay--Marfan's.

DR. WEISS: So do you want to amend that, Dr. Van Meter?

DR. VAN METER: Yes, I will drop homocysteneria and just put primary zonular dehiscence such as Marfan's.

DR. GRIMMETT: After I spelled it, too.

[Laughter.]

DR. WEISS: Dr. Smith.

DR. SMITH: Janine Smith. I'm sorry. Are you saying now you want specific indications then? Only the diseases that were in this study?

DR. VAN METER: No, these are guidelines.

DR. SUGAR: Examples.

DR. SMITH: Okay. Guidelines.

DR. VAN METER: These are guidelines as a for instance in the physician information booklet to help physicians who would be using the device for the first time.

DR. WEISS: Okay. Would you be able to just read that again for us, Dr. Grimmett, as it stands?

DR. GRIMMETT: Sure. Mike Grimmett. In the physician information booklet, include examples of possible indications for this device to include pseudoexfoliation, primary zonular weakness syndrome such as Marfan's, secondary zonular weakness syndrome such as trauma, and prior vitrectomy.

DR. WEISS: If there is no further discussion, I'd like to have a vote on this motion. All in favor, raise your hands.

[Show of hands.]

DR. WEISS: Nine in favor. All opposed?

[Show of hands.]

DR. WEISS: One opposed. The motion passes. The other thing that we discussed was indications for explantation. Does anyone want to include that as a motion? Explantation?

DR. VAN METER: I think we do not include that as a motion because that is really a practice of medicine issue.

DR. WEISS: Okay. So we will not include that in the--

DR. VAN METER: But we have already specified we have instructions for implantation.

DR. SMITH: Explantation.

DR. VAN METER: We have instructions for explantation, but I do not think we need to put in indications for explantation.

DR. WEISS: Does anyone want to include in the physician's information booklet information as to rates of explantation? Or has that been included elsewhere?

DR. VAN METER: It should be included elsewhere.

DR. GRIMMETT: In the outcomes analysis data.

DR. SUGAR: It should be included in the

data that--

DR. WEISS: Okay. So both Dr. Sugar and Dr. Grimmett indicate that information is already present in the outcomes data.

DR. SMITH: Janine Smith.

DR. WEISS: Dr. Smith.

DR. SMITH: I don't think that we said instructions for explantation at the same time as we said physician instructions for implantation.

DR. WEISS: I think that was the original motion, but Dr. Grimmett can read it back to us.

DR. GRIMMETT: The original motion was provide data and information regarding the insertion and removal technique for the capsular tension ring.

DR. SMITH: Thank you.

DR. WEISS: I think I've come down to the bottom of the notes that I had taken while the reviewers were speaking. I would ask for help from the panel at this point if there are any other issues that have not been covered in labeling or in the physician's booklet or other information that would be requested from the sponsor?

Okay. Well, if all the motions are now discussed, what I'd like to do is have a final vote

with all in favor of the main motion, which I would ask if you could restate, Dr. Grimmett, and its conditions that we've already voted upon, to signify by raising their hand. So we will now restate the main motion before us.

DR. GRIMMETT: Sure. Mike Grimmett. Dr. Sugar moved to regarding PMA P010059 approvable with conditions for stabilization of the crystalline lens capsule in the presence of weak or partially absent zonules in patients aged 18 years of age or older.

DR. WEISS: Okay. So now we will vote on this main motion. Okay. Dr. Van Meter?

DR. VAN METER: Van Meter. I believe the initial motion was for absent or weak zonules or a floppy capsule. There were sort of three.

DR. WEISS: Dr. Sugar.

DR. SUGAR: That was your suggestion. The motion I made was as stated. You suggested that, but the motion that I made was the one that Mike just restated.

DR. VAN METER: Okay. That's fine.

DR. WEISS: Okay. Everyone is clear on the motion, and this will also include the conditions as were previously voted on and

discussed.

So we'll have a vote with raising of hands for all of those in favor of this motion, and then we will poll each individual member as far as why they decided what they did. Can we have a vote? All in favor of the main motion with the conditions as stated, please signify by raising your hand.

[Show of hands.]

DR. WEISS: We have eight in favor. All opposed, please signify by raising your hand.

[Show of hands.]

DR. WEISS: We have one opposed. And all abstaining?

[Show of hands.]

DR. WEISS: One abstaining. Okay. At this point, the PMA P010059 has been approved with conditions that have been outlined, and I would like to poll the panel for their votes.

POLLING OF PANEL VOTES

DR. WEISS: And we can start with Dr. Smith.

DR. SMITH: While there are--

MS. THORNTON: Can you speak into the microphone a little louder?

DR. SMITH: Sure. While there are many

flaws in the data that was presented, I do not see any extremely worrisome evidence of lack of safety. With the limited ability that we do have to ascertain IOL centration, I feel that it's appropriate for the panel to recommend approvable with the conditions that we outlined with the strict advice that those conditions should be met and should any additional information be obtained with those conditions, then a physician reviewer from the panel be able to review that material.

DR. WEISS: Dr. Van Meter.

DR. VAN METER: Van Meter. I voted approvable with conditions. I believe the device is safe and it's efficacious in a very narrow spectrum of patients without which we have no other comparable device to use. And I think it will be beneficial for some patients who would otherwise not be able to have a posterior chamber lens implanted in the capsular bag.

MR. WEISS: Dr. Ho.

DR. HO: Approvable with conditions. Poor study, poor execution, flawed from the beginning, I think. I think my suggestion to sponsor if future studies are going to be done, for example, for kids, that they consider a different primary

outcome.

Execution of the surgery is really the primary difference and the reason that surgeons keep asking for this, the ability to put a bag in a lens, I think, and I have little safety concerns, and for that I think it's approvable with the conditions that we mentioned.

DR. WEISS: Dr. Coleman.

DR. COLEMAN: Yes. I voted approvable with conditions and despite the poor measure of the outcomes and the data analysis and the data collection, I did feel that there was reasonable assurance of safety and also of efficacy.

DR. WEISS: Dr. Grimmett.

DR. GRIMMETT: Mike Grimmett. I abstained from the vote, and while I'm happy that as a clinician I will have a device to possibly try during zonular dehiscence, I found that the deficiencies in this PMA combined make the PMA difficult if not impossible to scientifically interpret. Given its disorganization and incomplete presentation, not holding the PMA to lofty standards of ARVO or research meetings, this is the poorest PMA I've witnessed in the three to four years I've been on the panel.

We're left with a study that seemingly amounts to a compilation of favorable testimonials from non-uniform investigators utilizing non-standardized data acquisition techniques.

And while I agree that cataract extraction with zonular dehiscence is a difficult situation, and no alternate advice exists for use intraoperatively, the only real conclusion I can draw is that the capsular tension ring sounds like a good idea, but I can't scientifically say much given the poor data management by the sponsor.

DR. WEISS: Dr. Bradley.

DR. BRADLEY: I voted in favor of this proposal with conditions. It seems that it's established some degree of safety, but I am concerned about these patients with worse than 20/40 acuity, and I think that's a genuine safety question, and hopefully that will be addressed with information that's going to be submitted to the panel.

DR. WEISS: Dr. Matoba.

DR. MATOBA: I voted approvable with conditions. I believe that it will be helpful in a small subset of patients and the other subset in which the ring may be used, perhaps it will do no

good, but I don't think it will do any harm. And so, therefore, I voted approval of it with conditions.

DR. WEISS: Dr. McMahon.

DR. McMAHON: I voted against acceptance of this PMA on the basis of a poor experimental design, marginal long-term accountability, the absence of a measurable efficacy outcome, and the marginal presentation of safety data.

Though the worldwide experience and the interest of the surgeon suggests that this is likely to be safe and probably an efficacious device, the PMA itself does not stand on its own in my opinion.

DR. WEISS: Dr. Sugar.

DR. SUGAR: I voted approval with conditions. Dr. Grimmett characterized the data earlier as garbage. I assume he did so to make it smell better than it does. Nonetheless, I feel that the device is not harmful. It is useful in limited circumstances.

DR. WEISS: Dr. Casey.

DR. CASEY: As an anterior segment, I've seen a number of patients myself that I think would benefit from this, and I think that while the data

was very lacking, the device appears to be safe and thus needs to be further developed.

DR. WEISS: Thank you. We're going to have comments from the consumer and industry representatives--just the consumer representative. Glenda Such, please.

COMMENTS FROM CONSUMER REPRESENTATIVE

MS. SUCH: I feel comfortable with the passage of it based on their being conditions, and the conditions that were outlined. I think it was thorough. I, as my first time here, was uncomfortable with what I was seeing in the data myself. And some inconsistencies. So I really do think that this deserves a chance.

I would like to see if any further studies were done on this, that more thorough, more consistent, information be presented and guidance along the way perhaps to be able to do that before it comes to the panel would be given to them.

FINAL PANEL COMMENTS

DR. WEISS: Are there any other comments from the panel?

DR. McMAHON: Jayne.

DR. WEISS: Dr. McMahon.

DR. McMAHON: I'd like to leave here with

some assurance that the 133 patients that potentially were implanted with this ring based upon intraoperative observation of zonulysis or instability were consented prior to implementation. I don't think anybody here yet has indicated that that is the case.

DR. WEISS: Dr. Rosenthal is going to address that.

DR. ROSENTHAL: That will be considered under the bio research monitoring inspection which will be scheduled, is scheduled. So you don't have to--that's part of a routine evaluation.

DR. McMAHON: Okay. Thank you.

DR. WEISS: Any other comments by the panel? If not, Sallie Thornton has some closing.

DR. ROSENTHAL: Could I just--

DR. WEISS: I'm sorry. Dr. Rosenthal.

DR. ROSENTHAL: Yeah. I would just like to thank the panel for their deliberation and their very keen observations and for dealing with what has amounted to a very challenging submission. Thank you very much.

DR. WEISS: Thank you. If there are no other comments, Sallie?

MS. THORNTON: Yes. Just a few

administrative items prior to leaving the table. I'd like to remind the panel that the package that I gave you this morning or that you brought with today's agenda, et cetera, will be collected and destroyed if you do not take it with you, because it will contain tomorrow's materials as well.

So please don't leave at the table, but please leave everything pertaining to this particular PMA on the table for collection and destruction.

And I'll see you back here tomorrow at 8:30.

[Whereupon, at 3:30 p.m., the meeting was recessed, to reconvene at 8:30 a.m., Friday, January 18, 2002.]